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10/644,106	08/20/2003	Johan F.M. Gijsbers	11738.00120	6509

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EXAMINER	
WACHTEL, EMILY L	
ART UNIT	PAPER NUMBER
4111	

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12/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/644,106	GIJSBERS ET AL.	
	Examiner	Art Unit	
	Emily Wachtel	4111	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) *1-22,26,32 and 44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-25, 27-31, 33-43, and 45-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20 November 2003 and 24 November 2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II claims 23-25, 27-31, and 33-43 and 45-50 in the reply filed on September 28, 2007 is acknowledged.

2. Claims 1-22, 26, 32, and 44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 28, 2007.

Specification

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

In the instant case the abstract exceeds 150 words.

4. The disclosure is objected to because of the following informalities:

Page 7 [21] line 1 --ion-odulated-- should be --ion-modulated

Page 12 [35] line 1 --distributional-- should be --distribution--

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 recites the limitation "said brain fluid pumping mechanism" (emphasis added) in part b) of the claim. In part a) of the claim a pumping mechanism with a fluid source consisting of the patient's brain and a source *other* (emphasis added) than the patients brain is recited. Therefore, the fluid is not necessarily brain fluid. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 29-31, 42-43, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Osterholm (U.S. Patent 4,445,500).

With regard to claim 29 Osterholm teaches **a system for controlling epileptic seizures**

comprising: a) a fluid pumping mechanism (Figure 13 the pumping mechanism is taken to encompass all individual pumps contributing to the fluid pumping in this instance pump 111 is being considered, Col. 12 lines 17-19), **having an input, coupled to a fluid source selected from the group consisting of a patient's brain and a source other a patient's brain, and having an output** (Figure 13 input is connected to the nutrient emulsion reservoir 100 - a source other than the patient's brain and an output connected to the chemical balancing unit 110)**; b) a fluid ion adjustment mechanism coupled to said output of said brain fluid pumping mechanism** (In Figure 13 the ion adjustment mechanism is taken to be the chemical balancing unit 110, it is connected to the output of pump 111. Further in Figure 1, fluid from the brain is monitored for potassium and sodium ion concentrations - monitor 34 Col. 13 lines 46-50, in this diagram chemical balancing, taken to be ion adjustment, is at unit 12. Col. 15 lines 38-41 - sodium, potassium, calcium, magnesium, and chloride ions are balanced in the nutrient emulsion, it is taken that these ions would be balanced in the chemical balancing unit.)**, said fluid ion adjustment mechanism having an output from which modulated ion-content fluid is produced** (Figure 13 - the balanced fluid is returned to the nutrient emulsion reservoir 100)**; and c) a catheter, having an input coupled to the output of said ion adjustment mechanism and having an output inserted into a predetermined region of a patient's brain, whereby modulated ion-content fluid can be injected into the brain** (Figure 13 - catheter 120 is connected to the nutrient emulsion reservoir which is the output for the fluid from the ion adjustment mechanism and is output into the patients brain, Col. 12 lines 30-31 and 34-35)**.**

With regard to claim 30 the catheter includes dual lumens (Figure 13 catheter 120, Col. 12 line 34). This catheter is being used in place of cannula 20a (Figure 1) which carries the input

stream of the nutrient emulsion (Col. 12 lines 27-29) which carries the balanced fluid. This is input into a localized region of the patient's brain (Figure 1lateral ventricle 20, Col. 12 line 33).

With regard to claim 31 in Figure 13 pump 107, taken to be part of the overall pumping mechanism, (Col. 11 lines 58-59) has variable speed delivery and establishes the final injection rate into the brain (Col. 12 line 17). The flow rate at which the fluid is pumped is monitored by unit 38 in Figure 1 and then predetermined by unit 18 in Figure 1 to establish a desired flow rate (Col. 14 lines 32-34).

With regard to claim 42 the catheter comprises a tip with an arrangement of outlet holes disposed as a series of slits radially spaced around the tip (Col. 12 lines 50-52).

With regard to claim 43 the catheter provides the fluid to the lateral brain ventricle (Figure 1 ventricle 20, Col. 12 lines 30-35).

With regard to claim 45 the fluid is directly injected into the predetermined location of the lateral ventricle (Figure 1 ventricle 20, Col. 12 lines 30-35).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osterholm (U.S. Patent 4,445,500) as applied to claim 29 above and further in view of Lucido et al. (U.s. Patent 6,402,941).

With regard to claim 33 Osterholm teaches that the ion concentration is monitored (Col. 9 lines 11-13), as the concentrations are monitored they must be being measured, however, he does not disclose the means for doing this. Lucido teaches a conductivity sensor which measures ion concentration (Col. 8 lines 42-43). It would have been obvious to a person of ordinary skill to use conductivity as a means for measuring ion concentration in the device of Osterholm as it is a known method of measuring ion concentrations and would yield the predictable result of measuring the ion concentration.

With regard to claim 34 Osterholm teaches that pump 107 in Figure 13 (Col. 11 lines 58-59) has variable speed delivery and establishes the final injection rate into the brain (Col. 12 line 17). It would have been obvious to one of ordinary skill in the art that this would be a means for adjusting the delivery of the modulated ion-content fluid.

11. Claims 35, 38, and 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osterholm (U.S. Patent 4,445,500) as applied to claim 29 above, and in view of applicant admitted prior art (AAPA).

With regards to claims 35 and 38 AAPA discloses using the Goldman equation as a well-known equation for calculating the membrane potential (Page 9 [23]), therefore it would have been obvious to calculate the ion concentration using this equation as in claims 35 and 38 in order to be able to monitor the concentration so the system can determine how the fluid needs to be balanced. With regard to claim 35 Osterholm teaches that pump 107 in Figure 13 (Col. 11 lines 58-59) has variable speed delivery and establishes the final injection rate into the brain

(Col. 12 line 17). It would have been obvious to one of ordinary skill in the art that this would be a means for adjusting the delivery of the modulated ion-content fluid.

With regard to claims 46-48 AAPA discloses using ion exchange mechanisms of filtration and chemical treatment are well-know methods in the art for adjusting the ion concentration of a fluid (Page 6 [17]). While the device in Osterholm does not disclose what chemical balancing occurs to balance the ion concentration of the fluid it would have been obvious to a person of ordinary skill in the art to use filtering or chemical treatment to balance the ion concentration as it is an art recognized means for doing so in order to balance the fluid to the appropriate desired ion concentration.

12. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Osterholm (U.S. Patent 4,445,500) in view of Lucido et al. (U.s. Patent 6,402,941).

With regard to claim 49 AAPA discloses using ion exchange mechanisms of filtration and chemical treatment are well-know methods in the art for adjusting the ion concentration of a fluid (Page 6 [17]). While the device in Osterholm does not disclose what chemical balancing occurs to balance the ion concentration of the fluid it would have been obvious to a person of ordinary skill in the art to use filtering or chemical treatment to balance the ion concentration as it is an art recognized means for doing so in order to balance the fluid to the appropriate desired ion concentration. In the device of Osterholm fluid is injected into the brain and continuously circulate and withdrawn, as it is withdrawn it is continuously monitored and controlled (Col. 6 line 26, Col. 14 lines 3-4, lines 58-60, claim 1 part d). It is pumped into a localized region of the patient's brain in the lateral ventricle (Figure 1 ventricle 20, Col. 12 lines 30-35). Further, in the device of Osterholm fluid that was injected into the brain circulates and then is withdrawn and

monitored, effectively the brain fluid proximate to the region where the fluid in Osterholm is injected is monitored (Col. 13 lines 44-47). Osterholm teaches the fluid is monitored for ion concentrations however, Osterholm does not disclose a means for monitoring as in how the monitoring device actually monitors the ion concentration. Further as a means for monitoring, Lucido teaches a conductivity sensor which measures ion concentration (Col. 8 lines 42-43). It would have been obvious to a person of ordinary skill to use conductivity as a means for monitoring ion concentration in the device of Osterholm as it is a known method of measuring ion concentrations and would yield the predictable result of measuring the ion concentration so that the device could monitor them.

Double Patenting

13. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

14. Claim 23 rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6,551,301. This is a double patenting rejection. The wording between the two claims is slightly different, claim 1 of prior U.S. Patent No. 6,551,301 stated input

adapted to be coupled and an output adapted to be coupled (lines 4 and 15) and an ion adjustment mechanism for adjusting the ion-concentration of fluid (lines 6-7). Regarding the adapted to language it is being coupled to the brain in both claims and the brain is not an actual part of the apparatus or system, further it is known that the ion adjustment mechanism is adjusting the ion-concentration in both claims. It stands that the scope of the claims is the same and the same invention is being claimed.

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 24-25, 27-31, 33-43, and 45-50 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, and 5-21 of U.S. Patent No. 6,551,301. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Claim 15 of the patent recites a computer controlled pump, this computer control is reasonably expected to be reading and executing a program within the computer as in claim 24 of the application.

Claim 8 of the patent recites a probe for measuring conductivity or resistance of brain fluid, this is also reasonably expected to be related to the measurement of ion-concentration as in claim 25. Further, in claim 11 of the patent requires closed loop feedback means for delivery of the fluid, it would have been obvious to one of ordinary skill in the art that computer control is used in the closed loop feedback and it is controlling fluid delivery as in claim 25 of the application.

Claims 6 and 9 of the patent recite calculating the ion concentration using the Goldman equation, which is a membrane potential equation, it would have been obvious to one of ordinary skill in the art to calculate this using a computer as in claims 27 and 28 of the application.

Claim 1 of the patent recites the limitations of claim 29 of the application except that it does not include the limitation of a source other than the patient's brain. However, claim 29 recites that the source is selected from either the patient's brain or a source other than the patient's brain. Since one of those is in claim 1 claim 29 is obvious in light of claim 1.

Claim 2 of the patent recites a catheter returning fluid to a localized region of the patient's brain it would have been obvious to one of ordinary skill in the art that this catheter must have a fluid passageway as in claim 30 of the application if it is returning the fluid.

Claim 31 of the application is obvious over claim 3 of the patent as the fluid in claim 31 is brain fluid as in claim 3.

It would have been obvious to one of ordinary skill in the art that the fluid returned in claims 5, 8, 10, and 13 of the patent is injected into the brain as in claims 33, 37, 39, and 42 of the application respectively.

It would have been obvious to a person of ordinary skill in the art that the brain fluid pumping mechanism and fluid ion adjustment mechanism of claims 5, 7, and 12 in the patent are the same as the fluid pumping and fluid adjustment mechanisms in claims 34, 36, and 41 of the application respectively.

Claim 6 of the patent recites calculating the ion concentration using the Goldman equation it would have been obvious to one of ordinary skill in the art that this is the membrane potential equation as in claim 35 of the application. Further, it would have been obvious to a person of ordinary skill in the art that the brain fluid pumping mechanism of claim 6 in the patent is the same as the fluid pumping mechanism in claim 35 of the application.

It would have been obvious to one of ordinary skill in the art the to use the Goldman equation to calculate the ion-concentration as in claim 38 of the application as it is done in claims 6 and 9 of the patent.

Claims 11, 14, 16-19, and 21 recites the same limitations as claims 40, 43, 45-48, and 50 respectively.

Claim 20 in the patent recites the limitations of means for substantially continuously extracting fluid from the brain of the patient, then other limitations are recited in claim 49 of the application, making claim 49 obvious in view of claim 20.

Claims 23-25, and 27-28 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17-20 of U.S. Patent No. 6,447,500.

Although the conflicting claims are not identical, they are not patentably distinct from each other because

Claim 17 of the patent recites limitations found in claims 23 and 29 of the application and additionally recites the limitation of means for diagnosing an epileptic condition, the device in claims 23 and 29 would have been obvious to a person of ordinary skill in the art in view of claim 17.

Claims 18-19 of the patent recite the same limitations as claims 24-25 of the application.

Claim 20 in the patent recites using computer control to calculate ion concentration using the Goldman equation as in claim 28 of the application which is a membrane potential equation as in claim 27 of the application.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Wachtel whose telephone number is (571) 270-3648. The examiner can normally be reached on Monday through Thursday 7:30 AM to 5:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sam Yao can be reached on (571) 272-1224. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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